Remarks

The specification and abstract have been amended to correct spelling/idiomatic errors.

Claims 1, 19 and 20, which are the only independent claims in the application, have each been amended to recite the function of the dietary fiber as facilitating suspension of components of the medicinal liquid and stabilizing the suspension. Support for this is apparent throughout the specification, and more specifically in the first paragraph on page 4.

In the Final Rejection mailed July 7, 2003, the Examiner rejected claims 1-22 under 35 U.S.C. §103(a) as being unpatentable over Miskel et al. in view of Tanner et al. Applicants take the position that this rejection should be withdrawn, in view of the following considerations.

The Examiner takes the position that Miskel et al. teach a soft capsule comprising a water-soluble dietary fiber (citrus pectin) and a material of limited-oil solubility, without the presence of an dispersion stabilizer and fat and oil material or oil-soluble material.

However, the citrus pectin, which the Examiner says is a dietary fiber, is used as a part of the material for the macromolecular gel-lattice matrix to gelate an aqueous solution or suspension contained within the matrix. In the final form of the soft capsule of Miskel et al., the macromolecular gel-lattice matrix has become a rigid gel system.

On the other hand, in the presently claimed invention, as set forth in amended claims 1, 19 and 20, the dietary fiber facilitates suspension of the components of the medicinal liquid and stabilizes the suspension, thus being different from the citrus pectin (dietary fiber) of Miskel et al.

The Examiner acknowledges Applicants' argument that Miskel et al. teach a rigid gel rather than a liquid suspension, but the Examiner notes that Miskel et al. disclose a suspension at column 3, lines 40-44.

However, although the disclosure at column 3, lines 40-44 of Miskel et al. teaches a stable soft gelatin capsule having a water-containing solution or suspension of an active ingredient in the fill, the more detailed disclosure at column 3, lines 48-52 states that the capsule contains a fluid or semi-fluid fill composed of a macro-molecular gel-lattice matrix as a carrier for the aqueous solution or suspension of a chemical compound or medicament. A similar disclosure in set forth at the bottom of column 3, indicating that the gel-lattice matrix contains the aqueous solution or suspension.

Thus, in accordance with Miskel et al., the dietary fiber is not part of the aqueous solution or suspension, but rather, is part of the rigid gel system formed when the gel-lattice matrix is cooled (column 4, lines 1-6).

On the other hand, in accordance with the present invention, the medicinal liquid is a homogenized suspension containing both the dietary fiber and the material of limited oil-solubility (e.g. medicament). This is in contrast to Miskel et al. in which the dietary fiber is not in a homogenized suspension with the aqueous solution or suspension of the medicament, but rather, the dietary fiber is part of a rigid gel system which forms a matrix for the aqueous solution or suspension of the medicament.

One of the advantages of the present invention is that it permits the capsule to have a higher content of the material of limited oil-solubility (e.g. medicament), as noted in the first full paragraph on page 7 of the specification. There is absolutely no suggestion in Miskel et al. that this advantage could be achieved by incorporating the dietary fiber in the suspension of the material of limited oil-solubility.

The Examiner recognizes that Miskel et al. do not teach a homogeneous mixture of the medicinal liquid in the soft capsule. The Examiner then applies the Tanner et al. reference for a teaching of homogenization of actives and solubilizing agents, and the Examiner takes the position that it would have been obvious to make a soft gel capsule comprising citrus pectin to achieve high stability in view of Miskel. As to the claimed homogenization, the Examiner argues that Tanner et al. teach that homogenization is well known in the art of making a soft gel capsule, and that one of ordinary skill in the art would recognize that homogenization provides a stable mixture.

However, in the present invention, the homogenized suspension contains the dietary fiber, whereas in Miskel et al. the rigid gel system contains the dietary fiber. It is this rigid gel system that forms a matrix for the medicament. If the contents of the soft gel capsule of Miskel et al. were homogenized as suggested by the Examiner, the result would be to destroy the rigid gel system, i.e. matrix, which represents the inventive concept of Miskel et al. References cannot properly be combined if the effect of such combination would destroy the invention on which one of the references is based. Ex parte Hartmann, 186 USPQ 366. The only way to achieve a homogenized

suspension of the contents of the soft capsule of Miskel et al. would be to destroy the matrix, i.e. rigid gel system. Accordingly, one of ordinary skill in the art would not combine the references in the manner suggested by the Examiner.

For these reasons, Applicants take the position that the presently claimed invention is clearly patentable over the applied references.

Therefore, the application is now considered to be in condition for allowance, and such allowance is solicited.

Respectfully submitted,

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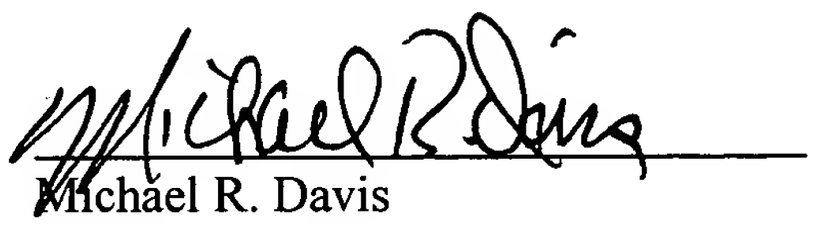
By: 

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ABSTRACT OF THE DISCLOSURE

A soft capsule capable of being substantially free of or having a minimum content of a fat and oil material and an emulsifier in an encapsulated liquid or medicinal liquid. The soft capsule contains a dietary fiber in an amount of 5 to 90% by weight based on a whole composition of the medicinal liquid.